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8	BEFORE THE BOARD OF REGISTERED NURSING	
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA	
10		<u>.</u>
11	In the Matter of the Accusation Against:	Case No. 2011-365
12	TONYA LEE BURKE	
13	16253 Lakeshore Drive Lake Elsinore, CA 92530	ACCUSATION
14	Registered Nurse License No. 492306	
15	Respondent.	
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17	Complainant alleges:	
18	PARTIES	
19	1. Louise R. Bailey, M.Ed., RN (Complainant) brings this Accusation solely in her	
20	official capacity as the Interim Executive Officer of the Board of Registered Nursing, Department	
21	of Consumer Affairs (Board).	
22	2. On August 31, 1993, the Board issued Registered Nurse License Number 492306 to	
23	Respondent Tonya Lee Burke. The Registered Nurse License was in full force and effect at all	
24	times relevant to the charges brought herein, and will expire on April 30, 2011, unless renewed.	
25	JURISDICTION	
26	3. This Accusation is brought before the Board under the authority of the following	
27	laws. All section references are to the Business and Professions Code (Code) unless otherwise	
28	indicated.	
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- 4. Section 2750 of the Code provides, in pertinent part, that the Board may discipline any licensee, including a licensee holding a temporary or an inactive license, for any reason provided in Article 3 (commencing with section 2750) of the Nursing Practice Act.
- 5. Section 2764 of the Code provides, in pertinent part, that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary proceeding against the licensee or to render a decision imposing discipline on the license. Under section 2811, subdivision (b) of the Code, the Board may renew an expired license at any time within eight years after the expiration.

#### STATUTORY PROVISIONS

- 6. Section 2052 of the Code states in pertinent part
- (a) Notwithstanding Section 146, any person who practices or attempts to practice, or who advertises or holds himself or herself out as practicing, any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended certificate as provided in this chapter or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense, punishable by a fine not exceeding ten thousand dollars (\$10,000), by imprisonment in the state prison, by imprisonment in a county jail not exceeding one year, or by both the fine and either imprisonment.
- (c) The remedy provided in this section shall not preclude any other remedy provided by law.
- 7. Section 2053.5 of the Code states in pertinent part:
- (a) Notwithstanding any other provision of law, a person who complies with the requirements of Section 2053.6 shall not be in violation of Section 2051 or 2052 unless that person does any of the following:
- (1) Conducts surgery or any other procedure on another person that punctures the skin or harmfully invades the body.
- 8. Section 2725 of the Code states in pertinent part:
- (a) In amending this section at the 1973-74 session, the Legislature recognizes that nursing is a dynamic field, the practice of which is continually evolving to include more sophisticated patient care activities. It is the intent of the

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Legislature in amending this section at the 1973-74 session to provide clear legal authority for functions and procedures that have common acceptance and usage. It is the legislative intent also to recognize the existence of overlapping functions between physicians and registered nurses and to permit additional sharing of functions within organized health care systems that provide for collaboration between physicians and registered nurses. These organized health care systems include, but are not limited to, health facilities licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, clinics, home health agencies, physicians' offices, and public or community health services. . . . .

- (b) The practice of nursing within the meaning of this chapter means those functions, including basic health care, that help people cope with difficulties in daily living that are associated with their actual or potential health or illness problems or the treatment thereof, and that require a substantial amount of scientific knowledge or technical skill, including all of the following:
- (2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.
- (4) Observation of signs and symptoms of illness, reactions to treatment, general behavior, or general physical condition, and (A) determination of whether the signs, symptoms, reactions, behavior, or general appearance exhibit abnormal characteristics, and (B) implementation, based on observed abnormalities, of appropriate reporting, or referral, or standardized procedures, or changes in treatment regimen in accordance with standardized procedures, or the initiation of emergency procedures.
- (c) "Standardized procedures," as used in this section, means either of the following:
- (1) Policies and protocols developed by a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code through collaboration among administrators and health professionals including physicians and nurses.
- (2) Policies and protocols developed through collaboration among administrators and health professionals, including physicians and nurses, by an organized health care system which is not a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

The policies and protocols shall be subject to any guidelines for standardized procedures that the Division of Licensing of the Medical Board of California and the Board of Registered Nursing may jointly promulgate. If promulgated, the guidelines shall be administered by the Board of Registered Nursing.

9. Section 2725.1 of the Code states, in pertinent part:

Notwithstanding any other provision of law, a registered nurse may dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a licensed clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of, or within a clinic as defined in subdivision (b) or (c) of Section 1206, of the Health and Safety Code.

No clinic shall employ a registered nurse to perform dispensing duties exclusively. No registered nurse shall dispense drugs in a pharmacy, keep a pharmacy, open shop, or drugstore for the retailing of drugs or poisons. No registered nurse shall compound drugs. Dispensing of drugs by a registered nurse, except a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51 or a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, shall not include substances included in the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code). Nothing in this section shall exempt a clinic from the provisions of Article 13 (commencing with Section 4180) of Chapter 9.

(2) Direct and indirect patient care services, including, but not limited to, the administration of medications and therapeutic agents, necessary to implement a treatment, disease prevention, or rehabilitative regimen ordered by and within the scope of licensure of a physician, dentist, podiatrist, or clinical psychologist, as defined by Section 1316.5 of the Health and Safety Code.

# 10. Section 2761 of the Code states, in pertinent part:

The board may take disciplinary action against a certified or licensed nurse or deny an application for a certificate or license for any of the following:

- (a) Unprofessional conduct, which includes, but is not limited to, the following:
- (d) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violating of, or conspiring to violate any provision or term of this chapter [the Nursing Practice Act] or regulations adopted pursuant to it.

#### 11. Section 2762 of the Code states, in pertinent part:

In addition to other acts constituting unprofessional conduct within the meaning of this chapter [the Nursing Practice Act], it is unprofessional conduct for a person licensed under this chapter to do any of the following:

(a) Obtain or possess in violation of law, or prescribe, or except as directed by a licensed physician and surgeon, dentist, or podiatrist administer to himself or herself, or furnish or administer to another, any controlled substance as

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1	defined in Division 10 (commencing with Section 11000) of the Health and Safety Code or any dangerous drug or dangerous device as defined in Section 4022.	
2	••••	
3	REGULATORY PROVISIONS	
4	12. California Code of Regulations, title 16, (Regulations) section 1470, states:	
5	The Board of Registered Nursing in conjunction with the Medical Board of California (see the regulations of the Medical Board of California, Article 9.5,	
7	Chapter 13, Title 16 of the California Code of Regulations) intends, by adopting the regulations contained in the article, to jointly promulgate guidelines for the development of standardized procedures to be used in organized health care systems which are subject to this rule. The purpose of these guidelines is:	
9	(a) To protect consumers by providing evidence that the nurse meets all requirements to practice safely.	
10	(b) To provide uniformity in development of standardized procedures.	
11	13. Regulations, section 1471, states:	
12	For purposes of this article:	
13 14	(a) "Standardized procedure functions" means those functions specified in Business and Professions Code Section 2725(c) and (d) which are to be performed according to "standardized procedures";	
15 16	(b) "Organized health care system" means a health facility which is not licensed pursuant to Chapter 2 (commencing with Section 1250), Division 2 of the Health and Safety Code and includes, but is not limited to, clinics, home health agencies, physicians' offices and public or community health services;	
17 18 19	(c) "Standardized procedures" means policies and protocols formulated by organized health care systems for the performance of standardized procedure functions.	
20	14. Regulations, section 1472, states:	
21	An organized health care system must develop standardized procedures	
22	before permitting registered nurses to perform standardized procedure functions. A registered nurse may perform standardized procedure functions only under the	
23	conditions specified in a health care system's standardized procedures; and must provide the system with satisfactory evidence that the nurse meets its experience,	
24	training, and/or education requirements to perform such functions.	
25	15. Regulations, section 1474, states:	
26	Following are the standardized procedure guidelines jointly promulgated by the Medical Board of California and by the Board of Registered Nursing:	
27 28	(a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.	

- (b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ,II "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.
- 18. Botox is a dangerous drug that can be dispensed only upon a prescription, as defined by and pursuant to Code section 4022. Botox (*Botulinum* Toxin Type A) Botox Cosmetic is a purified protein produced by the *Clostridium botulinum* bacterium, which reduces the activity of the muscles that cause frown lines between the brows to form over time when injected under the skin.
- 19. Restylane is a dangerous drug that can be dispensed only upon a prescription, as defined by and pursuant to Code section 4022. Restylane is composed of non-animal stabilized hyaluronic acid, a substance found naturally in the human body. Restylane is injected using a fine needle into the dermis below the wrinkle and lifts the wrinkle out to the desired correction.
- 20. Radiesse is a dangerous drug that can be dispensed only upon a prescription, as defined by and pursuant to Code section 4022. Radiesse is composed of synthetic calcium hydroxylapatite suspended in a gel carrier of sterile water for injection, glycerin and sodium carboxymethylcellulose. Radiesse should be injected with a 25 to 27 gauge needle and is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, and is also intended for restoration and/or correction of the signs of facial fat loss in people with human immunodeficiency virus.
- 21. Juvederm is a dangerous drug that can be dispensed only upon a prescription, as defined by and pursuant to Code section 4022. Juvederm injectable gel is a sterile, biodegradable, non-pyrogenic, viscoelastic, clear, colorless, homogenized gel implant, composed of crosslinked hyaluronic acid formulated to a concentration of 22-26 mg/mL, suspended in a physiological buffer. Depending on its formulation, Juvederm should be injected using a 27-30 guage needle, and is indicated for volumizing and correction of facial folds and wrinkles.

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### **FACTS**

- 22. From on or about February 22, 2005, until sometime between February 26, 2010, and October 1, 2010, Respondent was the sole owner, President/Executive Officer, and agent for service of process of Skin Oasis, Inc., California Secretary of State business entity number C2725154, with its principal place of business at 265 San Jacinto River Road, #105, Lake Elsinore, and which was issued a business license for that business name and address by the City of Lake Elsinore. Anasa Spa (Anasa) is the current principal occupant of 265 San Jacinto River Road, #105 in Lake Elsinore. Respondent leases a room at Anasa on a month-to-month basis, and pays a "weekly flat rate", to include utilities.
- Anasa was previously known as Samaria Salon and Spa (Samaria), a cosmetology establishment licensed by the Board of Barbering and Cosmetology (BBC) from August 25, 2005, until August 31, 2007, under BBC establishment license no. 235765. While Respondent leased space from Samaria, she advertised various procedures offered by "Tonya Burke, RN, Medical Esthetic Nurse Specialist," and her advertisements also noted that, "Services are medically supervised by Dr. C.S., Plastic Surgeon." Dr. S., M.D., who is licensed by the California Medical Board, has been and is a resident of and practices in Utah and does not maintain a medical office in California. Nevertheless, on January 10, 2006, Respondent and Dr. S. executed an "Agreement" that required Dr. S., as a "Medical Director," to "be available physically and in a timely manner to consult with clients as needed," among other obligations to Respondent. In furtherance of that Agreement, on June 1, 2007, Respondent and Dr. S. executed a series of documents purporting to be "Standardized Procedures and Protocols for Hair Removal & Fotofacial with McCue VPL," "Levulan with Fotofacial using McCue VPL," "Sclerotherapy Treatment by a Registered Nurse," "Administration of Botox by a Registered Nurse," Mesotherapy Treatment by a Registered Nurse," "Chemical Peel Treatment by a Registered Nurse," "Dermal Fillers Treatment by a Registered Nurse," and "Cosmelan Depigmentation Treatment." Respondent's advertising, online and in print, offers each of these services to the public.

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- 24. When interviewed by the Board's investigator on April 14, 2010, Respondent stated that when Dr. S. comes to California four to six times per year, he does so primarily to practice in Beverly Hills, though he works out of Respondent's Lake Elsinore office to a lesser extent. Although their agreement requires Dr. S. to see patients if the need arises, Respondent stated "that situation has never presented itself," and Dr. S. has not seen any of Respondent's clients/patients, nor done any consults for her with them. Dr. S. gives Respondent verbal feedback but no written feedback, evaluations or recommended changes.
- 25. Because it would take Dr. S. at least twelve hours to travel to California, Dr. K.S., D.O., who is licensed as an osteopath in California and whose offices are located in Newport Beach, approximately 58 miles from Lake Elsinore, is used by Respondent and Dr. S. as their "immediate back up doctor," though there is no written agreement with Dr. K.S., and Respondent has not reviewed her written protocols or consent forms with Dr. K.S.; their arrangement is all verbal. In the event of an emergency, though Dr. K.S. could come to Respondent's office, or her client/patient could go to his office, it takes approximately one hour's driving time to travel the distance between them, if not more.
- 26. On or about March 2, 2010, Respondent incorporated her business, Skin Oasis Aesthetics, Inc. (SOAI), California Secretary of State business entity number C3282091 in the state of California, with its principal place of business at 265 San Jacinto River Road, #105, Lake Elsinore, CA 92530. In addition to being SOAI's agent for service of process, Respondent is a 49% shareholder in SOAI, and yet another licensed medical doctor, Dr. T.S., M.D., is the majority 51% shareholder.
- 27. In her April 14, 2010 interview, Respondent admitted performing Botox injections; injecting dermal fillers; using Restylane, Juvederm, and Radiesse; and performing sclerotherapy (vein removal using saline injections) as part of her business/practice. She purchased these dangerous drugs directly from major manufacturers, and purchases two to three bottles of Botox every three to four months, approximately twelve bottles per year, via telephone order directly to Allergan, and the Botox is shipped to her place of practice. Respondent is the only one at her facility who performs these procedures. She also admitted giving B6 and B12 injections to "one

or two" clients/patients. Respondent admitted that Dr. S. does not see her clients/patients prior to her administering the injections, none of them have been examined by a physician, and none have been prescribed any of the medications Respondent administered to them. Respondent advertises in writing for "weight loss shots," but denies using vitamin B6 and B12 injections for this purpose, claiming she promotes them as "energy shots," while admitting that she "goes over weight loss information" with her clients/patients. Respondent also admitted that Dr. S. does not see her clients/patients prior to administering these injections

# FIRST CAUSE FOR DISCIPLINE

# (Unprofessional Conduct: Practicing Medicine Without a License)

28. Respondent is subject to disciplinary action under Code section 2761, subsections (a) and (d) in that by prescribing and administering Botox, Restylane, Radiesse, and Juvederm, dangerous drugs as defined in Code section 4022, and by injecting cosmetic fillers, saline solution, and vitamins B6 and B12 into patients, she engaged in the unlicensed practice of medicine, by treating patients without proper direction by a physician, and without prescriptions for the dangerous drugs she injects, as prohibited by Code sections 2052, 2053.5, subsection (1), 2725, and 2725.1, as detailed in paragraphs 22 through 27.

# SECOND CAUSE FOR DISCIPLINE

# (Unprofessional Conduct: Administering Dangerous Drugs Without Physician's Order)

29. Respondent is subject to disciplinary action for unprofessional conduct under Code section 2761, subsection (d) in that she dispensed Botox, Restylane, Radiesse, and Juvederm, dangerous drugs as defined in Code section 4022, to patients without an order therefor from a licensed physician, in violation of Code section 2725, subsection (b)(2), as detailed in paragraphs 22 through 27.

### THIRD CAUSE FOR DISCIPLINE

## (Unprofessional Conduct: Violation of Statutes and Regulations)

30. Respondent is subject to disciplinary action under Code section 2761, subsection (d) in that by prescribing and administering Botox, Restylane, Radiesse, and Juvederm, dangerous drugs as defined in Code section 4022, and by injecting cosmetic fillers, saline solution, and

1	vitamins B6 and B12 into patients, she violated the provisions of Code sections 2725, and 2725.1,	
2	and Regulations, sections 1472 and 1474, because the "standardized procedures" established by	
3	her and Dr. S., were not provided to patients in a health facility, clinic, or organized health care	
4	system allowing for their use, as detailed in paragraphs 22 through 27.	
5	FOURTH CAUSE FOR DISCIPLINE	
6	(Unprofessional Conduct: Obtaining, Possessing, Prescribing, Administering or Furnishing	
7	Dangerous Drugs)	
8	33. Respondent is subject to disciplinary action under Code section 2762, subsection (a)	
9	in that she obtained, possessed, prescribed, administered or furnished Botox, Restylane, Radiesse,	
10	and Juvederm, dangerous drugs as defined in Code section 4022, to patients and treated patients	
11	with those drugs without a prescription, detailed in paragraphs 22 through 27.	
12	PRAYER	
13	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,	
14	and that following the hearing, the Board of Registered Nursing issue a decision:	
15	1. Revoking or suspending Registered Nurse License Number 492306, issued to Tonya	
16	Lee Burke;	
17	2. Ordering Tonya Lee Burke to pay the Board the reasonable costs of the investigation	
18	and enforcement of this case, pursuant to Code section 125.3; and	
19	3. Taking such other and further action as deemed necessary and proper.	
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21	DATED: 10/25/10 Louise L. Bailey	
22	LOUISE R. BAILEY, M.ED., RN Interim Executive Officer	
23	Board of Registered Nursing Department of Consumer Affairs	
24	State of California SD2010701495  Complainant	
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